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K 012610

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ALLIANCE
MEDICAL CORPORATION

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510(k) Summary of Safety and Effectiveness

Submitter: Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact: Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation: August 5, 2001

Name of device: Alliance Medical Corporation Reprocessed Polypectomy Snares

Manufacturer	Device Description	Models
C.R. Bard, Inc.	Optimizer™ Polypectomy Snare	00472, 00473, 000475, 00477, 00479
Boston Scientific	Microvasive® OneSnare™ Polypectomy Snare	6206, 6208
Boston Scientific	Microvasive® Captivator™ Polypectomy Snare	6131, 6230
Boston Scientific	Microvasive® Captiflex™ Polypectomy Snare	6240, 6242
Boston Scientific	Microvasive® Sensation™ Polypectomy Snare	6265, 6267, 6269
Olympus America, Inc	Disposable Electorsurgical Snare	SD-210U-10, SD-210U-15, SD-210U-25
Wilson Cook® Medical, Inc.	AcuSnare® Polypectomy Snare	ASM-1, SAS-1, SASJ-1, SASM-1

K#	Device Description	Procode
K950496	Boston Scientific Microvasive® Single-Use Polypectomy Snare	FDI
K941750	Boston Scientific Microvasive® Polypectomy Snare	FDI
K955650	Olympus SD Series Snares	FDI
K923031	Cook Urological Endosnare	FDI
K955650	Olympus SD Series Snares	FDI
K902735	Olympus SD Snares	GEI
K945016	Bard Davol Polypectomy Snare	KOG

Device description: Polypectomy snares are specially designed endoscopic instruments composed of a handle and a wire cable with a loop for use in the endoscopic excision of gastrointestinal polyps. An active cord connects the monopolar polypectomy snare to a variety of monopolar generators. When activated, the loop of the snare will cut and cauterize tissue using monopolar electrical current.

Intended use: Reprocessed polypectomy snares are intended to be used endoscopically to remove and cauterize polyps and other tissue in the gastrointestinal tract.

Indications statement: Reprocessed polypectomy snares are indicated for use in patients requiring removal and cauterization of polyps in the gastrointestinal tract.

Technological characteristics: The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the submitted device(s) and the predicate device(s) have the same materials and product design. The technological characteristics of the submitted reprocessed polypectomy snares are the same as those of the legally marketed predicate devices.

Alliance Medical Corporation reprocessing of polypectomy snares includes removal of adherent visible soil and decontamination and thorough rinsing of all cleaning agents. Complete removal of residual moisture is accomplished using forced-air drying. Each individual instrument is tested for electrical continuity and appropriate extension of the snare loop prior to packaging, labeling, and sterilization operations.

Performance data: Performance data demonstrates that Reprocessed Polypectomy Snares perform as originally intended.

Conclusion: In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (Reprocessed Polypectomy Snares) is safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2002

Mr. Don Selvey
Vice President
Regulatory Affairs and Quality Assurance
Alliance Medical Corporation
10232 South 51st Street
PHOENIX AZ 85044

Re: K012610
Trade/Device Name: Alliance Preprocessed Polypectomy Snares (see attached list)
Regulation Number: 21 CFR § 876.4300
Regulation Name: Endoscopic electrosurgical Unit and accessories
Regulation Class: II
Product Code: 78 FDI
Dated: November 14, 2001
Received: November 28, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012610

Indications for Use Statement

510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Polypectomy Snares

Indications for Use: Reprocessed polypectomy snares are indicated for use in patients requiring removal and cauterization of polyps in the gastrointestinal tract.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use ____
(per 21 CFR 801.109)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012610